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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566
23980 7590 05/27/2010 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C One Financial Center BOSTON, MA 02111				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,103

Applicant(s)

SINGH ET AL.

Examiner

Isis A. Ghali

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 40-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 40-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/22/2010.

Claims 1-59 previously presented, claim 39 currently canceled, and claim 60 is currently added.

Claims 1-38 and 40-60 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

1. Claim 8 is objected to because of the following informalities: the claim is improperly identified as (currently amended), while no amendment made to the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-38, 40-41 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Therriault et al. (US 4,904,247) and Inaba et al. (US 4,552,751).

Applicant Claims

Applicants' claim 1 is directed to composition comprising

- (1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer;
- (2) active agent, and
- (3) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Therriault teaches laminate structure wherein each layer comprising composition for topical delivery of active agent comprising plasticized hydrophilic blend of polymers forming hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties (abstract; co1.2, lines 29-38; co1.3, lines 65-68). The reference teaches the layers comprised of 40- 80% of water soluble polymer selected from homopolymer of N-vinyl lactam or copolymers of N-vinyl lactam including polyvinyl pyrrolidone, 20-60% of water insoluble acrylic or methacrylic polymers, and 20-40% of plasticizer (co1.4, lines 1-41,53-68; co1.5, lines 1-30, 57-63). The plasticizer is polyethylene glycol having MW between 200-800 that disclosed by applicants as the complementary oligomer. Drugs and medicaments can be included into the composition (co1.3, lines 22-24). The

claimed amounts of each component overlaps the ranges taught by the reference, and the reference further teaches that properties of the hydrophilic blend such pressure sensitive property or non-tacky property is determined by the proportions of the hydrophilic polymer and plasticizer (co1.5, lines 10-20). Therefore, one having ordinary skill in the art would have been motivated to adjust the amount of individual polymers in order to achieve the desired properties of adhesiveness, absorbency, etc., according to the specific intended use.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Therriault teaches multi-laminate of hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties, however, Therriault do not specify that erodible backing layer as claimed by instant claim 1.

Inaba teaches multilayered film preparation that dissolves in body fluid, the film comprises active agent storage layers comprise one or more of: 10-80% water soluble polymer, 10-30% plasticizer that reads on the claimed oligomer, and drug. Inaba further teaches drug release controlling layer comprises water soluble and water insoluble polymers, which reads on the erodible backing layer (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51; claim 1). The water soluble polymer comprises hydroxymethyl cellulose, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene

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glycol, propylene glycol, polyethylene glycol or polypropylene glycol, all currently claimed as oligomer (col.2, lines 12-28). The erosion of the layer that controls the release of the active agent and made of water insoluble polymer is expected to be slower than layer containing water soluble polymers. The time of erosion of the multilayered film depends on the percentage of water soluble, water insoluble, and plasticizers. The multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose (abstract, col.1, lines 450-50).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Therriault, and replace one layer of the laminate with a layer that have slower solubility and erosion comprising cellulose derivatives as taught by Inaba. One would have been motivated to do so because Inaba teaches that multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose. One would reasonably expected formulating laminate wherein one layer of the laminate comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer

comprises polymer having slower erosion to provide long lasting release pattern of the active agent.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 02/22/2010 have been fully considered but they are not persuasive.

Applicants argue that the interpretation given by the examiner to claim 1, given in the Listing of the Claims, is incorrect as the claim has further limitations. It is improper for the Office to neglect claim limitations whether it be for obviousness or anticipation.

In response to this argument, it is argued that it is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359,1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*,

358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). Further, the currently standing rejection has addressed every limitation of each claim.

Applicants argue that Inaba teaches away from the use of gels. Therriault on the other hand is concerned with compositions comprising hydrogels and the present claims also require a hydrogel. The combination of Therriault with Inaba is consequently improper. "It is improper to combine references where the references teach away from their combination." There is no prima facie case of obviousness arising from the combination of Therriault with Inaba.

In response to this argument, it is argued that, as applicants admit, Therriault as well as the present invention are both concerned with compositions comprising hydrogels. Inaba is relied upon for the solely teaching of erodible backing for a device used for topical delivery, irrespective of the other layers of the device. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Inaba is in the field of applicant's endeavor, and furthermore reasonably pertinent to the particular problem with which the applicant was concerned, which is delivery of active agent topically from a device comprising erodible film giving no extraneous feeling. For this reason Inaba is relied upon as a basis for rejection of the claimed invention. Inaba therefore does not teach away from the present invention. "A reference may be said to

teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994). This is not the case with Inaba because Inaba teaches erodible backing of topical delivery device, as previously discussed.

Applicants argue that the Action does not establish that the combination of Therriault and Inaba produces the invention as claimed, including the limitation that "the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel." The Action merely states, without reasoning, that "The erosion of the layer that controls the release of the active agent and made of water insoluble polymer is expected to be slower than layer containing water soluble polymers."

In response to this argument, it is argued that Inaba teaches multilayered film that has different time of erosion of the different layers and provides the desired long lasting release pattern at a required concentration required for therapeutic purpose, see in particular the abstract and col.1, lines 450-50. Inaba disclosed drug storage layer between two layers that Inaba called them "drug release controlling layers", and at least one of these layers reads on backing layer. Each layer has different composition to

provide different erosion time, as stated above. The drug release controlling layers are taught by the reference to be made of the same material applicants claiming to use to make the eroding backing layer. Therefore, such layers will have the same erosion time, since materials and their properties are inseparable.

The combination of Therriault and Inaba teaches the invention as a whole. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Therriault, and replace one layer of the laminate with an erodible layer comprising cellulose derivatives as taught by Inaba. One would have been motivated to do so because Inaba teaches that multilayered film that has different polymer composition of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose. One would reasonably expect formulating laminate wherein one layer of the laminate comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises erodible polymer to provide long lasting release pattern of the active agent.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraid v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of

elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that the release controlling layer in Inaba is not a backing member as understood by those of skill in the art. In delivery of actives it is well understood that a backing member is one which lies behind the layer in contact with the

surface to which the actives are to be delivered, not one which lies between these and the surface and is used to control the rate of drug release. Inaba, because of its focus on intravaginal suppositories which apparently contact on both sides mucosa to which prostaglandins are to be delivered, does not make use of any backing member, so it is not appropriate to call on Inaba for teachings of a backing member.

In response to this argument, it is hereby repeated that Inaba teaches multilayered film that has different time of erosion of the different layers to provide the desired long lasting release pattern at a required concentration required for therapeutic purpose, see in particular the abstract and col.1, lines 450-50. Inaba disclosed the drug storage layer between two layers that Inaba called them "drug release controlling membrane". However, each layer has different composition and expected to provide different erosion time, as stated above. At least one of the drug release controlling layer is not necessary in contact to the surface of application (mucosa or skin) and reads on backing layer. The drug release controlling layers are taught by the reference to be made of the same material applicants claiming to use to make the eroding backing layer. Therefore, such layers will have the same erosion time, since materials and their properties are inseparable.

Regarding the argument that Inaba focused on intravaginal delivery, it is argued that Inaba teaches delivery to mucus membranes in general, and mentioned intravaginal route. Further Inaba teaches films and not suppositories, as applicants assert. In any events, the disclosed examples and preferred embodiment do not

constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Applicants' attention is directed to the scope of the present claims that is directed to a composition, and all the elements of the composition are taught by the combination of Therriault and Inaba. The drug release controlling erodible layer taught by Inaba reads on the erodible backing.

Applicants argue that the Action also states that "Inaba teaches that multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose." This contention is not accompanied by any cite to Inaba. Inaba does not say anything about the relative time of erosion of the different layers making up its suppositories, let alone anything about the relation of such relative times of erosion to the "desired long lasting release pattern at a required concentration required for therapeutic purpose.

In response to this argument, it is argued that Inaba teaches different composition of the drug release controlling layers and the drug containing layer, and teaches the drug release controlling layers comprising cellulose polymers, same material applicants claiming to use to make the eroding backing layer. Erosion of the drug release controlling layer taught by the reference will be the same as instantly claimed since materials and their properties are inseparable. Result-effective variables, such as dissolution rate can be optimized. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized

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result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 1-38, 40-41 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Therriault et al. (US 4,904,247) combined with Tapolsky et al. (5,800,832).

Applicant Claims

Applicants' claim 1 is directed to composition comprising

- (1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer;
- (2) active agent, and
- (3) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Therriault teaches laminate structure wherein each layer comprising composition for topical delivery of active agent comprising plasticized hydrophilic blend of polymers forming hydrophilic layers being capable of forming hydrogel and characterized by high

absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties (abstract; co1.2, lines 29-38; co1.3, lines 65-68). The reference teaches the layers comprised of 40- 80% of water soluble polymer selected from homopolymer of N-vinyl lactam or copolymers of N-vinyl lactam including polyvinyl pyrrolidone, 20-60% of water insoluble acrylic or methacrylic polymers, and 20-40% of plasticizer (co1.4, lines 1-41,53-68; co1.5, lines 1-30, 57-63). The plasticizer is polyethylene glycol having MW between 200-800 that disclosed by applicants as the complementary oligomer. Drugs and medicaments can be included into the composition (co1.3, lines 22-24). The claimed amounts of each component overlaps the ranges taught by the reference, and the reference further teaches that properties of the hydrophilic blend such pressure sensitive property or non-tacky property is determined by the proportions of the hydrophilic polymer and plasticizer (co1.5, lines 10-20). Therefore, one having ordinary skill in the art would have been motivated to adjust the amount of individual polymers in order to achieve the desired properties of adhesiveness, absorbency, etc., according to the specific intended use.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Therriault teaches multi-laminate of hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties, however, Therriault do not specify that erodible backing layer as claimed by instant claim 1.

Tapolsky teaches erodible pharmaceutical device for application to the mucosal surface, the device comprising one adhesive layer and backing layer (abstract). Both layers are water soluble, i.e. erodible, and provide effective residence time and minimal discomfort and ease of use (col.3, lines 20-33). The adhesive layer comprises one polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble polymer (col.3, lines 34-39; col.5, lines 37-60; example 11). The backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose or hydroxypropylmethyl cellulose (col.3, lines 40-45). The residence time of the device depends on the dissolution rate of the water soluble polymers, and the dissolution rate may be adjusted by adjusting the mixed amounts of the polymers, therefore the erosion time of the device claimed by claims 29-36 are expected to be obtained by adjusting the ratios of water soluble and water swellable polymers according to specific intended use (col.4, line 66-col.4, line 5). The film may contain therapeutic agent, flavoring agent and coloring agent (col.7, line6-col.8, line 10).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Therriault, and replace one layer of the laminate with the

erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the device having erodible backing layer provides effective residence time and minimal discomfort and ease of use. One would reasonably expect formulating laminate that is comfortable and easy to use and comprises one layer comprising hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises is erodible cellulose derivative and further adjust dissolution of the backing layer according to specific intended use and site of application.

Regarding the limitation of slower erosion of the backing layer than the hydrogel, Tapolsky teaches dissolution rate may be adjusted by adjusting the mixed amounts of the polymers. Therefore, one having ordinary skill in the art at the time of the invention would have been able to adjust the polymers to obtain the desired dissolution time of the backing layer according to the intended use and site of application.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

8. Applicant's arguments filed 02/22/2010 have been fully considered but they are not persuasive.

Applicants argue that the Action having misstated the content of the claims, ignores the limitation "the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel." If that limitation were taken into account rather than being ignored, then it would immediately be seen that the combination of references would not result in that which was claimed. Therriault does not teach the backing layer. Tapolsky does have a teaching of a backing layer, but it is the exact opposite of what is taught here: "the adhesive layer, will have a slower dissolution time, given that the backing layer protects the interior, adhesive layer and will dissolve first."

In response to these argument, it is repeated that the examiner did not misstated the claims, however gives the claims the broadest reasonable interpretation. It is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359,1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). Further, the currently standing rejection has addressed every limitation of each claim.

The limitation of erodible backing is given weight and is taught by Tapolsky. Tapolsky teaches erodible pharmaceutical device for application to the mucosal surface,

the device comprising one adhesive layer and backing layer (abstract). Both layers are water soluble, i.e. erodible. The backing layer comprises cellulose derivatives as instantly claimed. Slower erosion of the backing layer than the hydrogel is suggested by Tapolsky as the reference teaches dissolution rate may be adjusted by adjusting the mixed amounts of the polymers. Therefore, one having ordinary skill in the art at the time of the invention would have been able to adjust the polymers to obtain the desired dissolution time of the backing layer according to the intended use and site of application. In view of disclosing the same polymers instantly claimed, the erosion time is obvious over Tapolsky.

Tapolsky does not teach the opposite of the present claims because it teaches erodible film including the backing. Tapolsky teaches dissolution rate may be adjusted by adjusting the mixed amounts of the polymers. Therefore, one having ordinary skill in the art at the time of the invention would have been able to adjust the polymers to obtain the desired dissolution time of the backing layer according to the intended use and site of application. Result-effective variables, such as dissolution rate can be optimized. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

9. Claims 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the combination of Therriault and Inaba, or the combination of Therriault and Tapolsky, each combination further in view of Sagel et al. (US 5,891,453).

The combined teachings of Therriault and Inaba and the combination of Therriault and Tapolsky are previously discussed as set forth in this office action.

Although the combinations of the references teach active agent, however, the references do not teach teeth whitening material as claimed by claims 42-49, and teeth whitening method as claimed by claims 50-59.

Sagel teaches strip for teeth whitening comprising gel comprising tooth whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof (abstract, examples; claim 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein one layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises erodible polymer as taught by the combined teaching of Therriault and Inaba or Therriault and Tapolsky, and replace the active agent by teeth whitening agent selected from peroxides and metal chlorites as taught by Sagel. One would have been motivated to do so because Sagel teaches that such materials as preferred material for tooth whitening for inclusion in gel strips applied to the mucus membrane. One would reasonably expect formulating laminate wherein one layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent selected from

peroxide or metal chlorite that whiten teeth, and a second layer comprises polymer having slower erosion, wherein the laminate when applied to teeth will whiten the teeth effectively and safely with great success.

Response to Arguments

10. Applicant's arguments filed 02/22/2010 have been fully considered but they are not persuasive.

The combinations of references including Sagel are improper because the Action's statement begs the question of what would have motivated a person of skill in the art starting with Tapolsky, Inaba, or Therriault to take an interest in tooth whitening at all. Once you are into tooth whitening, it may make sense to choose your actives based on Sagel's teaching, but if your starting point is Tapolsky, Inaba, or Therriault, how do you decide on tooth whitening in the first place? Tapolsky claims anesthetic. There is quite an elaborate laundry list of actives in Tapolsky, but tooth whiteners do not make the cut. Therriault is likewise agnostic about just what pharmaceutical agent can be delivered. Inaba focuses on prostaglandins.

In response to this argument, it is argued that all the cited references: Therriault, Tapolsky, and Inaba, are directed to topical application, and the references are generic with regard to the delivered therapeutic agent. Sagel teaches tooth whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof delivered by topical application of gel. One having ordinary skill in the art would have determined the therapeutic agent to

deliver from the hydrogel taught by Therriault according to the condition to be treated. The disclosed examples and preferred embodiment of therapeutic agents taught by the references do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Further, it had been decided by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. *In re Lemin*, 141 USPQ 814 (1964); *National Distillers and Chem. Corp. V. Brenner*, 156 USPQ 163.

Applicants argue that the Action's reasoning also misstates Sagel's teachings: "the delivery system is placed on the surface of the teeth", not "applied to the mucous membrane" as the Action states. Tooth whitening systems only touch the mucous membranes in the mouth as a side-effect of their use. What is good for mucous membranes is not necessarily good for adhering to the teeth. Furthermore, a good backing member that lasts longer than the adhesive layer, as claimed here, may be designed to shield mucous membranes from the active in the adhesive layer.

In response to this argument, again all the cited references: Therriault, Tapolsky, and Inaba, are generic with regard to the therapeutic agent. The hydrogel composition of Therriault is suitable for topical drug delivery. Topical delivery reads on local delivery to any surface of application that can be surface of the teeth. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter.

1985). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988).

Applicants argue that the Action's statement regarding likelihood of success for the combinations with Sagel is purely conclusory. The statement relates to what the inventors have discovered, but it does not follow from Tapolsky, Theriault, Inaba or Sagel.

In response to this argument, it is argued that the likelihood of success is only a reasonable expectation of what suggest and not absolute prediction. Under U.S.C. 103 (a), a conclusion of obviousness does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). Further, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only

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from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is well established that the claims are given the broadest interpretation during examination. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that the Action does not provide the specific polymers for the backing member are recited in claims 8-16. Tapolsky recites only certain specific cellulose-derived polymers, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, and ethylene oxide-propylene oxide copolymers. No recitation there of "acrylate polymers, starches, alginic acid, alginates, polyamino acids" set out in claim 8, claims 12-16, and 60. Claim 40 requires that the backing layer be impermeable to the active agent. The rate controlling membrane of Inaba would not be so impermeable. The backing layer of Tapolsky is one in which the active agent "may be included." There would be no purpose in including the active agent in that layer unless it could get out and do its job, in which case the backing layer could not be impermeable to it.

In response to this argument, it is argued that the materials of the backing as claimed by claims 8, 12-16, and 60, are all known in the art as biodegradable polymers

and one having ordinary skill in the art would recognized all of them as equivalent as evident by the teaching of US patent 6,548,081 for Sadozai, col.4, lines 9-47. Applicants failed to show superior and unexpected results obtained from using any one of the claimed polymers over the other or over those taught by the prior art. Regarding claim 40, it is noticed that the claimed biodegradable materials are taught by the cited references, therefore, expected to display the same properties as claimed, i.e. as being impermeable to the drugs.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

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0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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